

CLAIMS

1. A composition formulated for intramuscular injection comprising
a testosterone ester selected from the group of esters consisting of linear and branched C-
9 to C-16 alkanoates; and
5 a vehicle comprising castor oil and a co-solvent.
2. The composition according to claim 1, wherein the testosterone ester is selected from
the group consisting of testosterone esters of linear and branched noncanoates,
decanoates, undecanoates, dodecanoates, tridecanoates, tetradecanoates,
10 pentadecanoates, and hexadecanoates.
3. The composition according to claim 2, wherein the testosterone ester is testosterone
undecanoate.
- 15 4. The composition according to claim 1, wherein the vehicle comprises the castor oil in a
concentration of less than 50 vol%.
5. The composition according to claim 1, wherein the vehicle comprises said castor oil and
co-solvent in a volume ratio ranging between 1:0.2 to 1:3.
20
6. The composition according to claim 1, wherein the co-solvent is benzyl benzoate.
7. A method of treating diseases and symptoms associated with deficient endogenous
levels of testosterone in a man, comprising injectable administration of a testosterone
25 ester selected from the group of esters consisting of linear and branched C-9 to C-16
alkanoates, the method further comprises;
i) an initial phase comprising 2 to 4 injections of a dose of said testosterone ester with an
interval of 4 to 8 weeks between each injections, each dose is in an amount therapeutically
equivalent to a dose of testosterone undecanoate of between 500 mg and 2000 mg;
30 followed by
ii) a maintenance phase comprising subsequent injections of a dose of said testosterone
ester with an interval of at least 9 weeks between each subsequent injection, each dose is
in an amount therapeutically equivalent to a dose of testosterone undecanoate of between
500 mg and 2000 mg.
35
8. The method according to claim 7, wherein said initial phase comprises 2 injections of
said dose of said testosterone ester.
9. The method according to claim 7, wherein said interval is 6 weeks.

10. The method according to claim 7, wherein said subsequent injections of said dose is with an interval of 10 weeks.
- 5 11. The method according to claim 7, wherein said dose of said testosterone ester is in an amount therapeutically equivalent to a dose of testosterone undecanoate of between 750 to 1500 mg.
12. The method according to claim 7 wherein the man is a hypogonadal man, a man with
10 hypophyseal diseases or a man in therapy with gonadotropin-suppressive agents or progestins.
13. The method according to claim 7, wherein said diseases and symptoms is associated with primary and secondary hypogonadism and hypophyseal diseases.
- 15 14. The method according to claim 13, wherein said primary hypogonadism is derived from testicular failure associated with cryptorchidism, bilateral testicular torsion, orchitis, orchidectomy, Klinefelter syndrome, chemotherapy or toxic damage from alcohol or heavy metals.
- 20 15. The method according to claim 13, wherein said secondary hypogonadism is associated with idiopathic gonadotropin releasing hormone (GnRH) deficiency or pituitary-hypothalamic injury from tumours, trauma or radiation.
- 25 16. The method according to claim 7, further comprising administering a progestin or a further gonadotropin suppressive agent.
17. The method according to claim 16, for male contraception.
- 30 18. The method according to claim 7, wherein the testosterone ester is selected from the group consisting of testosterone esters of linear and branched noncanoates, decanoates, undecanoates, dodecanoates, tridecanoates, tetradecanoates, pentadecanoates, and hexadecanoates.
- 35 19. The method according to claim 18, wherein the testosterone ester is testosterone undecanoate.
20. The composition according to claim 1, wherein the vehicle comprises the castor oil in a concentration of less than 45 vol%.

21. The composition according to claim 1, wherein the vehicle comprises the castor oil in a concentration of less than 40 vol%.
- 5 22. The composition according to claim 1, wherein the vehicle comprises the castor oil in a concentration of less than 30 vol%.
23. The composition according to claim 1, wherein the vehicle comprises said castor oil and co-solvent in a volume ratio ranging between 1:0.5 to 1:3.
- 10 24. The composition according to claim 1, wherein the vehicle comprises said castor oil and co-solvent in a volume ratio ranging between 1:0.75 to 1:2.5.
25. The composition according to claim 1, wherein the vehicle comprises said castor oil and co-solvent in a volume ratio ranging between 1:1 to 1:2.
- 15 26. The method according to claim 7, wherein said subsequent injections of said dose is with an interval of 11 weeks between injections.
- 20 27. The method according to claim 7, wherein said subsequent injections of said dose is with an interval of 12 weeks between injections.
28. The method according to claim 7, wherein said dose of said testosterone ester is in an amount therapeutically equivalent to a dose of testosterone undecanoate of about 1000 mg.
- 25